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The impact of a mobile application-based treatment for urinary incontinence in adult women: Design of a mixed-methods randomized controlled trial in a primary care setting

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Aims: We aim to assess whether a purpose-developed mobile application (app) is non-inferior regarding effectiveness and cost-effective when used to treat women with urinary incontinence (UI), as compared to care as usual in Dutch primary care. Additionally, we will explore the expectations and experiences of patients and care providers regarding app usage.

Methods: A mixed-methods study will be performed, combining a pragmatic, randomized-controlled, non-inferiority trial with an extensive process evaluation. Women aged ≥ 18 years, suffering from UI ≥ 2 times per week and with access to a smartphone or tablet are eligible to participate. The primary outcome will be the change in UI symptom scores at 4 months after randomization, as assessed by the International Consultation on Incontinence Modular Questionnaire UI Short Form. Secondary outcomes will be the change in UI symptom scores at 12 months, as well as the patient-reported global impression of improvement, quality of life, change in sexual functioning, UI episodes per day, and costs at 4 and 12 months. In parallel, we will perform an extensive process evaluation to assess the expectations and experiences of patients and care providers regarding app usage, making use of interviews, focus group sessions, and log data analysis.

Conclusion: This study will assess both the effectiveness and cost-effectiveness of app-based treatment for UI. The combination with the process evaluation, which will

Anne M.M. Loohuis and Nienke J. Wessels have contributed equally to this work.

Dr. Mickey Karram led the peer-review process as the Associate Editor responsible for the paper.

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be performed in parallel, should also give valuable insights into the contextual factors that influence the effectiveness of such a treatment.

KEYWORDS

eHealth, mixed methods, mobile applications, randomized controlled trial, self-management, urinary incontinence, women

1 | BACKGROUND

eHealth, which represents health services and information delivered or enhanced through the internet and related technologies, is an emerging clinical resource with potential advantages for the treatment of urinary incontinence (UI).¹ In particular, the use of mobile health applications (apps) may increase adherence to treatment advice and thereby reduce costs.² Although conservative treatment is effective for UI, adherence varies from 18% to 95% and is one of the main problems in the treatment of UI.³ Also, total costs for absorbent materials, pelvic physiotherapy, medication, and specialist care are high.⁴ Currently, various apps have been designed to support the treatment of UI, but research on their effectiveness, quality, and usability is scarce.

Recently, the use of an app-based treatment for stress UI was assessed in Swedish women in a community setting, and not only produced clinically relevant symptom improvement but also reduced pad usage compared with postponed treatment.⁵ In other research, an internet-based training program was shown to be a cost-effective alternative for treating stress UI when compared with a treatment program sent by post.⁶ However, studies evaluating app-based treatment for all three types of UI (ie, stress, urgency, and mixed UI) are lacking, and app-based treatment for UI has never been compared to care as usual. Moreover, there is a lack of research into the experiences and preferences of important stakeholders, such as patients and care providers, which can often result in poor implementation of such eHealth solutions.⁷

Therefore, using a mixed-methods study design, we will evaluate an app-based treatment for stress, urgency, and mixed UI in women. Our aims in this study are twofold: first, we will assess whether a purpose-developed app is non-inferior and cost-effective in treating women with UI, as compared to care as usual in Dutch primary care; second, we will evaluate the expectations and experiences of patients and care providers regarding use of the app. By combining these results, we expect to provide valuable insights into the facilitators of, and barriers to favorable outcomes for mobile app use in the treatment of UI.

2 | METHODS

2.1 | Study design

In this mixed-methods study, a pragmatic, randomized-controlled, non-inferiority trial will be conducted in parallel with a process evaluation study (Figure 1). The randomized-controlled trial (RCT; Part A) is designed to study the non-inferiority and cost-effectiveness of an app-based treatment for UI, compared to care as usual in primary care.

We have chosen a pragmatic design because we want to provide the best reflection of the expected effect of the intervention under real-life conditions. We opted for non-inferiority because we wanted to show that the intervention is not less effective than the established treatment. This approach is recommended in light of the fact that eHealth interventions may offer additional advantages.⁸ We hypothesize that app-based treatment for women with incontinence will not be less effective than care as usual in primary care, and that it will increase the cost-effectiveness of treatment by reducing the need for face-to-face consultations with care providers such as general practitioners (GP) and pelvic physiotherapists. In the process evaluation (Part B), we aim to assess the experiences and expectations of patients and healthcare professionals regarding the use and implementation of the new app.

The RCT is registered in the Dutch Trial Register (registration number NTR21609), approval was obtained from the Medical Ethical Review board of the University Medical Center Groningen (UMCG), the Netherlands (METc-number: 2014/574). The Medical Research Involving Human Subjects Act (WMO) does not apply for the process evaluation, which has been confirmed by the Medical Ethical Review board of the UMCG (letter-number: M17.207954).

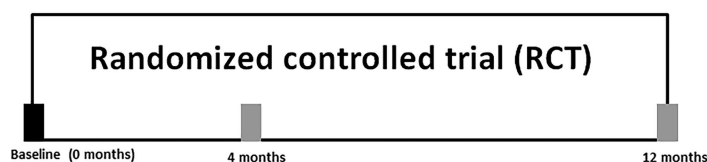
2.2 | Part A: The RCT

2.2.1 | Setting

Participants will be recruited in the northern part of the Netherlands. Recruitment has started in October 2015 through primary care practices. Additionally, as from

Part A

Randomized controlled trial



■ **Baseline assessment:** physical examination, questionnaires and frequency volume chart.

■ **Follow up:** questionnaires and frequency chart at 4 and 12 months

△ **Patient feedback:** on treatment adherence, level of exercise and progress of exercise at baseline, 4 and 12 months.

Part B

Process evaluation

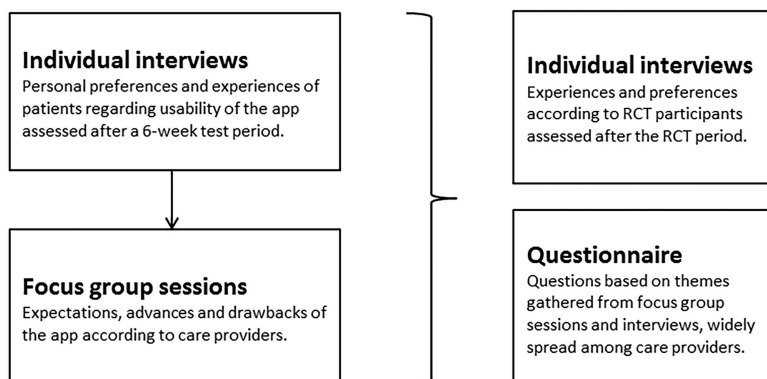


FIGURE 1 An overview of the mixed-methods for the URinControl study design. Part A shows the RCT with details of the planned baseline assessment and follow-up assessments at 4 and 12 months. Part B shows the planned process evaluation that will be conducted parallel to the RCT, and that will collect app usage data, patient feedback, patient interviews, focus group sessions and a questionnaire for care providers. Results from the usability study with patients and the focus group sessions will be used to develop a quantitative questionnaire and form an interview guide for a qualitative evaluation within the RCT

November 2017, participants are also recruited through lay press and social media attention and through the study website.

2.2.2 | Recruitment of participants

The process for participant recruitment is shown in Figure 2. We will use the following inclusion criteria: female sex; age ≥ 18 years; self-reported stress, urgency, or mixed UI at least twice a week according to the Three Incontinence Questions (3IQ, Appendix 2); wanting treatment; and access to a smartphone or tablet. Women are excluded in case of: indwelling urinary catheter, urogenital malignancy, previous surgery for UI, treatment for UI in the previous year (pharmacological or non-pharmacological), terminal or serious illness, cognitive impairment, or psychiatric illness, urinary tract infection (UTI) (dipstick, and if negative, dipslide or urine culture), overflow or continuous UI, pregnancy or recent childbirth (<6 months ago) or the inability to complete a questionnaire in Dutch. Eligibility is assessed by the patient's GP or by the research physician based on a patient history. As from November 2017,

urinalyses will only be performed in case of clinical suspicion of a UTI. Eligible women will be invited to participate with an information letter. Informed consent will be obtained by the researcher during baseline assessment.

2.2.3 | Randomization

After baseline assessment the researcher will randomize the participants using the validated web-based computer program ALEA.⁹ Block randomization with random block sizes will be applied at the GP level to correct for differences between GPs.

2.2.4 | Interventions

The URinControl App

Participants in the intervention group will have access to a smartphone or tablet app, which we named the URinControl App. This contains a step-by-step program for the treatment of each type of UI, mainly focusing on pelvic floor muscle and/or bladder training depending on the primary diagnosis (Appendix 1, Figure 3). The app will guide participants to the

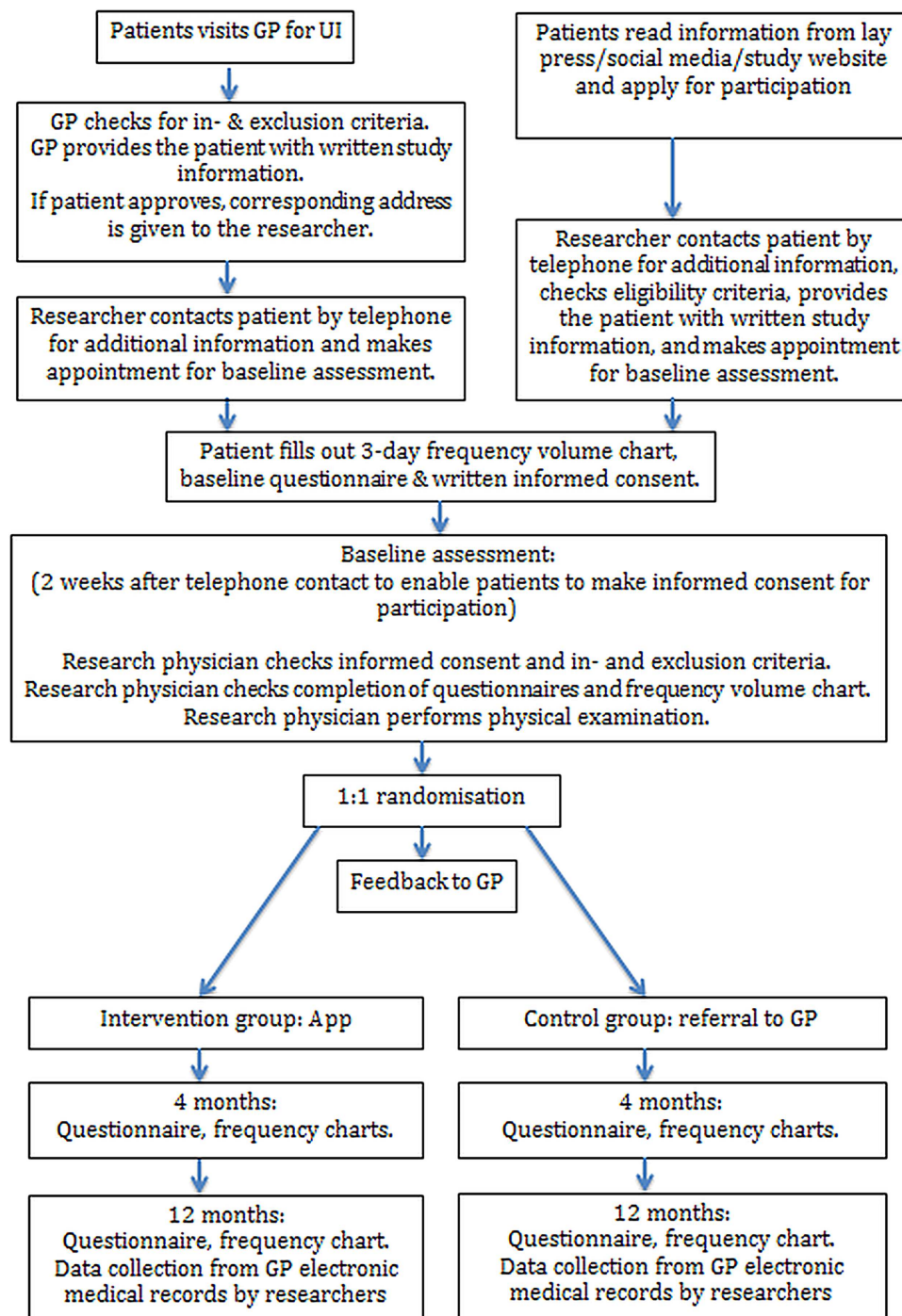


FIGURE 2 Flowchart of patient inclusion and assessments in the randomized-controlled trial (Part A). GP, general practitioner; UI, urinary incontinence

appropriate part of the app, to start directed training, and, if applicable, when to add the other type of training. Participants in the intervention arm will be asked to use the application as a self-management tool without caregiver involvement. The research team will only provide technical support, but the participant will be free to contact her GP regarding any questions regarding the medical aspects of her condition or treatment. The GP can then decide what additional support is needed, if any.

Care as usual (control group)

Participants in the control group will receive treatment according to the Dutch GP guideline on UI.¹⁰ They will be referred back to their GP who will discuss the various treatment options. The management plan can then vary depending on the preferences of patients and GPs, but may involve any of the following: instructions on pelvic floor muscle and/or bladder training; prescribing a pessary, drugs, or absorbent products; or referral to a continence nurse, a

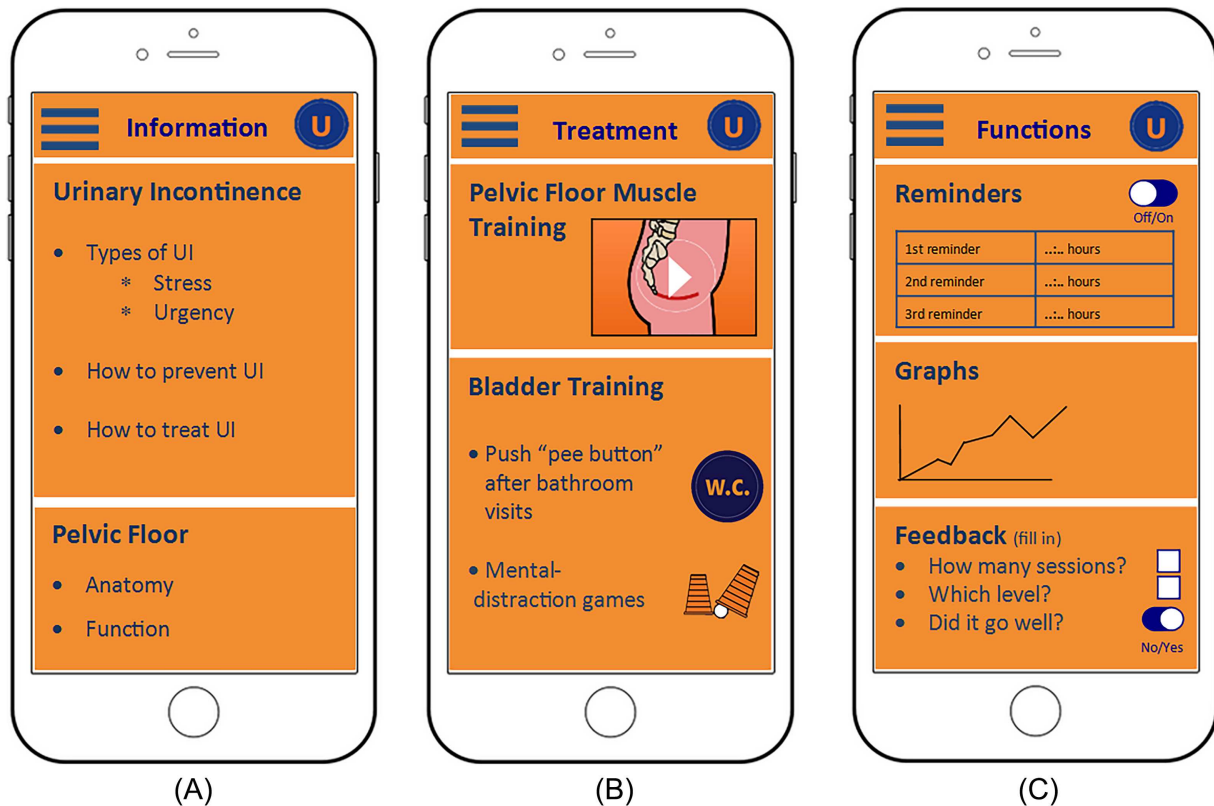


FIGURE 3 A schematic representation of the contents of the URinControl App. (A) Information on both types of urinary incontinence, prevention and treatment options, as well as information on anatomy and function of the pelvic floor. (B) Training programs for both stress and urgency urinary incontinence (pelvic floor muscle training and bladder training, respectively). (C) Functionalities of the App, including three reminder-options, the graph function, and a patient feedback option

pelvic physiotherapist, or to secondary care (ie, a urologist/gynecologist). Due to the pragmatic nature of this trial, referred patients will be treated according to current guidelines in these settings. Detailed information on the applied treatments will be collected.

2.3 | Measurements

2.3.1 | Baseline assessment

History and physical examination

After gaining informed consent, a research physician will assess age, parity, UI duration, comorbidity, and drug use, and will measure the participant's weight and height, and perform a baseline urogynecological assessment. Pelvic floor muscle function will be assessed according to recommendations of the International Continence Society, and the stage of pelvic organ prolapse will be assessed using the Pelvic Organ Prolapse Quantification (POP-Q) method.^{11,12}

Questionnaires

Participants will complete validated questionnaires on UI symptoms (the International Consultation on Incontinence

Modular Questionnaire UI Short Form, ICIQ-UI-SF); condition-specific (ICIQ-LUTS-QoL) and generic health-related (EuroQol questionnaire, EQ-5D-5L) quality of life; and the influence of incontinence on sexuality (Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, International Urogynecological Association-revised: PISQ-IR). Finally, a question on the use of absorbent pads and UI-specific healthcare will be added to the questionnaire set (Appendix 2).

Frequency volume chart

Participants will complete a three-day frequency volume chart that will be used to gain insight into the frequency of micturition, number of UI episodes, and volumes of urine voided per micturition.

2.3.2 | Follow-up assessment

At 4 and 12 months, all baseline questionnaires will be repeated. Participants will also complete a frequency chart (without volume measurements). Additionally, the Patient Global Impression of Improvement (PGI-I), for both incontinence and sexuality, will be administered. All medical cost items related to UI will be measured with the adjusted versions of the Institute of Medical Technology Assessment

Medical Consumption Questionnaire (iMTA-MCQ) and the Productivity Costs Questionnaire (iMTA-PCQ). After 12 months, data from the electronic medical records of GPs will be collected retrospectively to assess UI-specific costs, including that related to referrals, consultations with health-care professionals, prescribed medication and absorbent pads, and UI-associated comorbidity.

2.3.3 | App usage

We will monitor App usage by two types of data; data filled in by the participant and automatically logged data. Participants are invited to fill in whether they performed their exercises, at what level and if it went well. Actual activity is automatically logged; for example, data on opening/closing different exercise levels and duration of use.

2.3.4 | Primary outcome

The primary outcome of interest is the change in UI symptoms score assessed by the ICIQ-UI-SF at 4 months after randomization.

2.3.5 | Secondary outcomes

The secondary outcomes are as follows:

- Severity of UI (measured with the ICIQ-UI-SF) at 12 months.
- Patient's global impression of improvement (PGI-I) on UI and sexuality at 4 and 12 months.
- Condition-specific quality of life (assessed with the ICIQ-LUTS-QoL) at 4 and 12 months.
- Generic health-related quality of life (assessed with the EQ5D-5L) at 4 and 12 months.
- Condition-specific sexual functioning (assessed with the PISQ-IR) at 4 and 12 months.
- Number of UI episodes per day (derived from frequency charts) at 4 and 12 months.
- Costs at 4 and 12 months, measured with the adjusted iMTA-MCQ and iMTA-PCQ, and extracted from electronic medical records after 12 months.

2.3.6 | Blinding

Due to the nature of the interventions, blinding for treatment allocation is not feasible.

2.3.7 | Sample size

We have opted for a non-inferiority design, which means that the sample size calculation is based on the hypothesis

that the app-based treatment group will be inferior to the care as usual group (H_0 hypothesis). Rejection of this hypothesis leads to acceptance of non-inferiority (H_1 hypothesis). One recent study, using anchor-based methods to determine the minimal clinically important difference (MCID), identified a between-treatment MCID of 1.58 points among patients with stress UI.¹³ We therefore based the sample size calculation on an estimated non-inferiority margin of 1.5 points, a one-sided type I error of 0.025, and a power of 0.80. This generated a total requirement of 100 evaluable patients per group. Allowing for an expected loss-to-follow-up of up to 20%, we will require 250 patients for this study. We aim to have 90 participating GP's, who should include 2,5 patients each. We expect this to be achievable, since the incidence of UI in primary practice is 9.3 per 1000 patient years.¹⁴

2.3.8 | Analysis

Descriptive analyses

We will describe frequencies of stress, urgency, and mixed UI for the intervention and control groups, including analysis by age distribution, educational level, previous smartphone and/or tablet experience, recruitment strategy, and baseline questionnaire scores.

Analyses of clinical outcomes

A linear regression model will be used for non-inferiority testing, with adjustment for confounders if necessary. In case of non-inferiority, we will assess superiority with a two-sided test, using a significance level of $P < 0.05$. A missing value analysis will be performed and multiple imputation techniques will be used, as appropriate.

There is no gold-standard analysis in non-inferiority trials. Intention-to-treat (ITT) analyses, risk bias toward the null hypothesis.¹⁵ However, the alternative per-protocol (PP) analysis can cause bias in either direction by allowing patients to be excluded.¹⁵ Therefore, both ITT and PP analyses will be performed in this study.

Analysis of cost data

In the economic evaluation, the primary aim will be to estimate the societal costs of women with UI using an interactive app compared with the costs of care as usual following established guidance. Such a societal perspective incorporates direct and indirect healthcare costs, such as direct medical costs, patient and family costs, and costs due to productivity losses.¹⁶

A cost-effectiveness analysis (CEA) will also be performed from a societal perspective. We will use the incremental cost-effectiveness ratio (ICER) as a composite outcome score. The ICER will indicate the ratio of additional

costs or gains of treatment based on using the app, as well as the additional change in symptom score measured with the ICIQ-UI-SF, compared to care as usual. We will also perform a cost-utility analysis based on EuroQol 5D-5L defined utilities.¹⁷

2.4 | Part B: Process Evaluation

Process evaluations can improve the validity and outcome interpretation of RCTs to help refine an intervention.¹⁸ We therefore aim to conduct an extensive process evaluation to answer two research questions:

1. What are the experiences and expectations of patients and care providers regarding the use and implementation of our app-based management of UI?
2. What is associated with success or failure of the app-based management of UI?

To answer the first research question, we will conduct a usability study. To avoid influencing the RCT, we will recruit women who meet the inclusion criteria, but who do not participate in the RCT. Participants will be asked to use the URinControl App for 6 weeks, after which semi-structured interviews will be conducted to assess usability preferences and experiences. Additionally, focus group sessions will be held with relevant occupational groups (eg, GPs, practice assistants, pelvic physical therapists, and urogynecologists) and supplemented with one multidisciplinary focus group session. Results from the usability study will be used to provide additional input for these sessions. Focus group sessions will be exploratory in nature, so participants with a range of characteristics will be invited from local health facilities. Finally, the results from the usability study and focus group sessions will be used to develop a quantitative questionnaire that will be distributed among health professionals in the Netherlands to assess their opinions on the themes collected. This should provide a deeper understanding of the context in which future implementation of an app for UI should take place.

To answer the second research question, we will integrate the results of automatically logged usage data (log data) analysis, patient interviews, and quantitative results of the RCT. Log data will be gathered from the apps to provide a more in-depth insight into adherence.¹⁹ After 12 months' follow-up, patient interviews will be held, aiming to include approximately 40 participants from the RCT. The results from the previously described focus group sessions and usability study will be used to form an interview guide for this qualitative evaluation within the RCT. Additionally, during the RCT, participants will be asked to answer open-ended questions at baseline and follow-up regarding their personal view on the success or failure of treatment. By integrating these results with quantitative results of the RCT, we aim to

provide greater insight into the facilitators of, and barriers to, treatment success with the URinControl App.

2.5 | Analysis

The semi-structured interviews and focus group sessions will be recorded using a digital voice recorder and transcribed verbatim. Transcriptions will be coded using the Atlas.ti (Scientific Software Development program). Coding will be performed separately by two researchers and checked for agreement. Data analysis will be driven by an inductive approach, allowing themes to emerge from the data by constant comparison.

2.6 | Sample size

Participants will continue to be enrolled for individual interviews until no new themes emerge from the data (ie, saturation is reached).²⁰ The focus groups will be performed with care providers and consist of 6-8 people per session.

3 | DISCUSSION

This study will evaluate an app-based treatment of UI for women in primary care, using a mixed-methods design. The non-inferiority to care as usual, the cost-effectiveness, and the expectations and experiences of stakeholders will be evaluated. Ultimately, the study aims to provide more insight into the processes underlying the use and effectiveness of an app for managing UI, which should help to improve the development and implementation of this and future eHealth tools.

To the best of our knowledge this is the first proposal that seeks to evaluate an eHealth-treatment for stress, urgency, and mixed UI, and it is the first that aims to do so in a help-seeking population in primary care. Only two previous studies have assessed internet- and/or app-based treatment for stress UI. These studies differ from ours in terms of treatment comparison (either a group receiving postal information or a group receiving postponed treatment, rather than comparison to usual care).^{5,6}

The main strength of this study will be in the combination of research methods used. A mixed-methods study design is frequently used in social science and can make an important contribution to RCTs evaluating health service interventions.²¹ In our design, the quality of the process evaluation has been strengthened by applying the three methods described by Zhang et al, namely the *integration* of quantitative with qualitative data, *connecting* portions of the study in phases, and *embedding* a parallel conducted qualitative assessment alongside an RCT.²² Other strengths are the use of a non-inferiority design,

the evaluation of experiences of both patients and professionals throughout the process, the societal cost-effectiveness evaluation, and the use of log data analyses. The use of pragmatic effectiveness analyses will provide a realistic comparison between care as usual and app-based treatment, and the use of log data from the app will provide valuable information on actual app use, progress, and adherence. Together, this information is essential to anticipate whether implementation will improve healthcare outcomes.

Potential challenges lie in participant recruitment, notably because there are well-known barriers to women seeking help for UI.²³ Another possible limitation may lie in the use of a pragmatic design; indeed, the features that support the generalizability of the results to real-world practice may also limit the interpretation of the results.²⁴ These features include the lack of blinding and possible sub-optimal adherence to therapy. Research within eHealth is relatively young, and there is no gold-standard process for conducting a process evaluation in this field.

We believe that this study is unique in combining several current guidelines on study design with advice regarding process evaluation, both in general and within eHealth specifically.^{7,18,25} Therefore, this study design offers a multifaceted evaluation of an app-based eHealth intervention.

4 | FUTURE PERSPECTIVES

Although eHealth is a promising and emerging technology, urogynecology apps have not been adequately tested or compared to care as usual. Moreover, experiences and preferences of important stakeholders are often not explored, resulting in poor implementation.⁷ The results of this study will provide valuable insights into the contextual factors that influence the effectiveness of a mobile app in the treatment of UI and will provide useful information for the development and evaluation of future eHealth applications. If successful, the URinControl App will be made openly available for patients and health professionals, providing an easily accessible treatment option for women who experience barriers to asking for care.

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proposal in general practice, which included additional funding. The funders will have no role in data collection, analysis, decision to publish, or preparation of the manuscript.

CONFLICTS OF INTEREST

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Marijke Slieker-ten Hove reports: Consultant at Novuquare. Co-developer of a mobile application for the support of pelvic floor exercises ("App BekkenBodem") which is commonly available free of charge. Other authors have nothing to disclose.

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APPENDIX 1

URinControl App: contents and development

Main objectives

The program content is a translation of the recommendations of the guidelines on the treatment of female UI in primary care.¹⁰ Development of the URinControl App was

based on the following objectives: 1) to inform and educate the patient about UI; 2) to guide the patient through the main treatment exercises, without the need of instruction from a healthcare professional; 3) to increase adherence to exercises by integrating them in daily life; and 4) to give the patient insight into treatment progress (number and level of exercises performed over time). An overview of the contents of the URinControl App is shown in Figure 3.

Development and technical information

Members of the research project and its advisors, including physicians, pelvic physiotherapists, and patients, collaborated to develop the URinControl App program. The eHealth developers are experienced in the development of internet-based medical programs, and the program has been built on a secure platform, using a Secure Sockets Layer. During the study, the app will be exclusively available on the iOS™ (version 8.1) and Android™ (version 2.3.3) platforms through Therapieland B.V. (version 1.30 and 1.3), for patients in the intervention group. A pilot study was performed with patients suffering from UI to detect any irregularities and to review user-friendliness. Security and user-friendliness were also reviewed and approved by the committee of Medical Tools of the University Medical Centre of Groningen.

APPENDIX 2

Description of questionnaires

The International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF): This is a self-completed questionnaire that measures frequency, volume, and impact on daily life of involuntary urine loss. Scores range from 0 to 21, with higher scores correlating with worse incontinence. This questionnaire measures patient-reported outcomes in UI and is recommended by the International Consultation on Incontinence.

The Three Incontinence Questions (3IQ): This is a simple and quick questionnaire with acceptable accuracy for classifying urge and stress incontinence, appropriate for use in primary care. The questions correspond with the three questions recommended in the Dutch guideline on UI for assessing the type of incontinence (ie, stress UI, urgency UI, and mixed UI).

Condition-specific quality of life (ICIQ-LUTS-QoL): a psychometrically robust patient-completed questionnaire evaluating quality of life in patients with UI, which is used in research and clinical practice worldwide. It has received a Grade A recommendation from the International Continence Society for use in women with UI. The overall score ranges from 19 to 76.

Generic Health-related Quality of Life (EQ-5D-5L): This is a commonly used measurement of general health status, with good validity and reliability reported in various health conditions. Health states, as defined by the five-dimensional descriptive system of this questionnaire, will be converted into a weighted health state index, using the EuroQol crosswalk value set.

Patient-reported Global Impression of Improvement (PGI-I): This is a single item index, measured on a seven-point Likert scale (very much better, much better, a little better, no change, a little worse, much worse, very much worse)

Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, International Urogynecological Association-revised (PISQ-IR): This is the only instrument validated in both sexually active and sexually inactive women with pelvic floor dysfunction.

The Institute of Medical Technology Assessment-Medical Consumption Questionnaire and iMTA Productivity Costs Questionnaire (iMTA-MCQ and iMTA-PCQ): The adjusted versions of these questionnaires are used to measure the use of healthcare and non-healthcare resources.